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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,160

06/14/2005

Thomas Gradel

190-89

2690

2746

7590

02/11/2008

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

02/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,160	<b>Applicant(s)</b> GRADEL ET AL.	
	<b>Examiner</b> JAMES L. SWIGER	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/14/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

It is noted that the drawings provided by applicant do not support the claimed subject matter. Applicant claims an interior cavity that is closed toward the front by an anterior wall. NONE of the drawings, in any way, show a closed front. Fig. 5, at most shows the frontal side, but has an opening 13. Additionally, it appears that applicant, as it is unsupported by the specification, is claiming that the two side walls are of different widths. This is because applicant claims a transverse axis and then claims that the height varies along this axis.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 27 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A varying height along the transverse axis and an interior cavity closed toward the front anterior wall is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

See also comments above as noted in the drawing rejection.

It is noted that applicant's specification does not appear to teach a closed front end. Nowhere in the drawings is a closed front shown, as mentioned above. Further it is noted that applicant now directs the implant to having a longitudinal and transverse axis. The longitudinal axis is generally construed as the portion along the longer body length of the device, and the transverse is perpendicular to this arrangement. In light of this, a height that varies *along the transverse axis is being construed as the actual height*

*between the lateral walls.* Basically, if true, one lateral wall would be shorter than the other; this is not shown in the drawings.

Appropriate action is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-19, 21-23 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (Reference Pub. No.: 2002/0068976 A1) in view of Zdeblick et al. (US Patent 5,782,919).

Jackson discloses an intervertebral implant (1) comprising a solid biocompatible material implant body (5) having a tubular general structure delimited by an upper wall (15) and a lower wall (16), two opposite lateral walls (see Figure 1 below) that are plane and slightly divergent toward the front, and a posterior wall (17) with a threaded axial hole (50), with a single interior cavity (see Figure 1 below; paragraph 0036) providing communication between orifices provided in the upper wall (15) and the lower wall (16), wherein: the upper (15) and lower (16) wall each comprise a respective single large upper or lower orifice (45, 46), an interchangeable compression plug (6, 7, 8, 9; paragraph 0034); the interior cavity is closed toward the front by an anterior wall (see Figure 1 below), the width of the implant (1) defined by the lateral walls is less than its

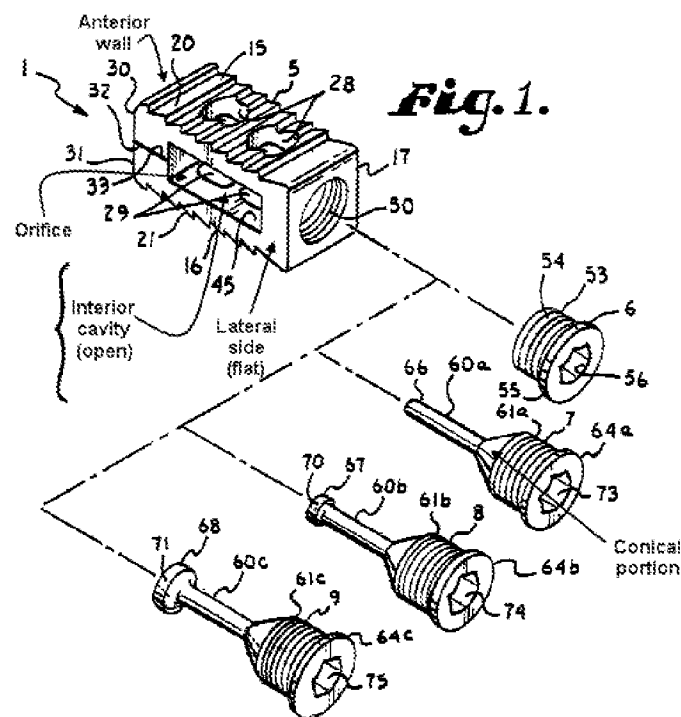
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height defined by the upper and lower wall. It is noted that Jackson's implant could also be cylindrical in shape (paragraph 0011), therefore allowing the width of the implant to be less than its height. Because of the upper and lower orifice, the interior cavity is open over the whole of its width between the lateral walls and over the whole of its length between the posterior and anterior wall (see Figure 1 below).

The interchangeable compression plug (6, 7, 8, 9) comprises a conical interior end portion (see Figure 1 below). The interchangeable compression plug (6, 7, 8, 9) and the threaded axial hole (50) that receives it have a diameter substantially equal to the width of the interior cavity in the vicinity of the posterior wall (see Figure 1 below). The interchangeable compression plug (6, 7, 8, 9) has a length such that, at the end of screwing it into the threaded axial hole (50) that receives it, its interior end portion penetrates the interior cavity to a distance of at least one quarter of the length of said interior cavity (paragraph 0041-0043). The implant (1) has at least two interchangeable compression plugs (6, 7, 8, 9; paragraph 0034) having different lengths (paragraph 0041). The anterior wall includes an eccentric threaded hole of smaller diameter (paragraph 0038). The upper and lower larger wall include annular toothed anti-expulsion ribs (paragraph 0037). The interchangeable compression plug is made of titanium (paragraph 0011). The upper (15) and lower wall (16) are each of conical general shape and the upper and lower orifice are each bordered at their anterior and posterior ends by a flat perpendicular to the lateral walls (see Figure 1 below).

It is noted that Jackson's invention is used between a pair of adjacent vertebrae in order to provide stabilization between the vertebrae that has been destabilized due to

injury. Also, the “expandable member” disclosed by Jackson is capable of compressing the implant into the vertebrae and therefore stabilizing the vertebrae. It is further noted that Jackson discloses that in some circumstances different members of windows may be provided in the upper and lower walls. Therefore, Jackson’s implant could have a single orifice instead of two smaller orifices.



Jackson discloses the claimed invention except for the upper and lower wall being convex and with a solid front that diverges. Zdeblick et al. disclose an intervertebral device that is convex in shape (see Fig. 2), and has a solid front wall (17, Fig. 10). The design helps to promote insertion and bone growth. See also Col. 5, lines 15-40).

The combination of Jackson and Zdeblick et al. disclose the claimed invention except for specifically the frontal, closed end diverging. It would have been obvious to one having ordinary skill in the art at the time the invention was made have the frontal end as the preferred end for divergence, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art, and is an obvious modification of design choice. In re Einstein, 8 USPQ 167.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Jackson having at least the upper and lower wall being convex and with a solid front that diverges in view of Zdeblick et al. to better install the implant in use.

Claims 24 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (Reference Pub. No.: 2002/0068976 A1) in view of Zdeblick et al. '919 and further in view of Brantigan (Reference U.S. Patent "5,425,772").

The combination of Jackson and Zdeblick et al. disclose the claimed invention except for the implant body made of a PEEK type polymer and the implant comprising titanium marker in the implant body away from the interchangeable compression plug. Brantigan teaches to provide an implant made of a PEEK type polymer (col. 3, lines 47-57) in order to reduce the affects of the compression and for promoting better bone fusion. Brantigan further teaches to provide the titanium markers in the implant body in order to visualization of postoperative bone healing. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of the



combination of Jackson and Zdeblick et al., having the implant body made of a PEEK type polymer and having titanium marker, in view of Brantigan, in order to reduce the affects of the compression, promote bone growth and for visualization of postoperative bone healing.

### ***Response to Arguments***

Applicant's arguments filed 8/20/2007 have been fully considered but are considered moot in view of the new grounds of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/  
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733